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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,926	11/18/2003	Christine Letitia Knox	10338-17US(12128060/VPA/a	5885

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EXAMINER	
SHEN, BIN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,926	KNOX ET AL.	
	Examiner	Art Unit	
	Bin Shen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18,22-45 and 48-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-18,22-45 and 48-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-18, 22-31, 41-44, drawn to a method for detecting the presence of an organism associated with an increased risk of different conditions.

II. Claims 32-34, drawn to a method for diagnosing a higher risk of different conditions.

III. Claims 35-39, drawn to an isolated adhesin.

IV. Claims 40, drawn to an isolated polynucleotide.

V. Claim 45, drawn to a method of screening for an agent.

VI. Claim 48, drawn to an antigen-binding molecule.

VII. Claim 49, drawn to a method of detecting an adhesion.

VIII. Claim 50, drawn to a method for prognostic assessment.

IX. Claim 51, drawn to a method for affecting an adhensin.

X. Claims 52-53, drawn to a method for modulating adherence of an organism.

XI. Claims 54-56, drawn to a composition.

XII. Claims 57, 58, 60, 61, 63, 64, 66-68, 70, 71, 77, drawn to a method for treatment using antisense oligonucleotide and a ribozyme.

XIII. Claims 57, 59, 60, 62, 63, 65, 67, 69, 70, 72, 78, drawn to a method for treatment using an antigen-binding molecule.

XIV. Claim 73, drawn to an immunopotentiating compound.

XV. Claims 74-76, drawn to a method for a treatment using an immunopotentiating compound.

1. The inventions are independent or distinct, each from the other because:

Product Groups of III, IV, VI, XI, XIV are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the polynucleotide of Group IV and antigen-binding molecule of Group VI are not disclosed as capable of use together and they have different designs (such as polynucleotide is comprised of nucleotides while an antigen-binding molecule comprised of amino acids), modes of operation, and effects as evidenced by the distinct structures and functions of the claimed inventions.

Because these inventions are distinct for the reasons given above and the search required for one group and not required for the other group, restriction for examination purposes as indicated is proper. Search any two of these groups together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claim in Group IV drawn to polynucleotide, must be searched in nucleic acid sequence commercial databases, while Group III drawn to an isolated adhesion, must be searched in amino acid sequence databases. Thus, these groups have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they are to be searched together.

The methods of Groups I, II, V, VII, VIII, IX, X, XII, XIII, XV are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects

(MPEP § 802.01 and § 806.06). In the instant case, the different methods of these groups are not disclosed as capable of use together and they have different designs, modes of operation, and effects as evidenced by the distinct method steps and different materials used in each group. Furthermore, the different method steps are used for different purposes or functions.

Because these inventions are distinct for the reasons given above and the search required for one group are not required for the other group, restriction for examination purposes as indicated is proper. Search and two of these groups together would present a search burden on the Examiner. For example, diagnosing method of Group II has different method steps, using different materials, when compared with treatment method of Group XIII. Thus, these groups have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they are to be searched together.

Products of Groups III, IV, VI, XI, XIV, and methods of Groups I, II, V, VII, VIII, IX, X, XII, XIII, XV, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, each of the products of Groups III, IV, VI, XI, XIV can be used in a materially different process of using that product as evidenced by the claims themselves. For example, an isolated adhesion of Group III can be used to study its interacting proteins, and an

isolated polynucleotide of Group IV can be used as a probe for cloning/subcloning.

Moreover, the searches required for product Groups are not required for the method groups. Thus, to search any one group from the method of Groups I, II, V, VII, VIII, IX, X, XII, XIII, XV, and any one from the product groups together would be unduly burdensome. For example, the product groups will be searched in their appropriate commercial databases, while the method steps will be searched for the method groups. Therefore, the product group and the method group are properly restricted from each other as being distinct and unduly burdensome to be searched together. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all

criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

3. This application contains claims directed to the following patentably distinct species: male infertility, an adverse pregnancy outcome, and an adverse assisted reproductive technology. The species are independent or distinct because they are different conditions with very different mechanisms and outcomes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from three different conditions (male infertility, an adverse pregnancy outcome, and an adverse assisted reproductive technology) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 35, 49, 50, 51, 52, and 73 are generic.

Claim 17 is generic to the following disclosed patentably distinct species: miscarriage, pre-term delivery, premature onset of labor, prolonged rupture of membranes, neonatal morbidity and mortality. The species are independent or distinct because each condition is independent and distinct with different symptoms and outcomes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 18 is generic to the following disclosed patentably distinct species: reduced embryonic development, reduced implantation rate, reduced fertilization rate, reduced clinical pregnancy rate, reduced viable pregnancy rate, reduced blastocyst culture rate and increased miscarriage rate. The species are independent or distinct because each condition is independent and distinct with different symptoms and outcomes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 28 is generic to the following disclosed patentably distinct species: artificial insemination, in vitro fertilization and intracytoplasmic sperm injection. The species are independent or distinct because each technology is independent and distinct with different method steps and using different materials. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are

generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in

compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify

applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

MICHAEL MELLER
PRIMARY EXAMINER

B Shen
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